

## **VII. 510(k) Summary of Safety and Effectiveness**

In accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92, GIMMI GmbH is hereby submitting the 510(k) Summary of Safety and Effectiveness for AlphaXenon Light (510(k) number K093125).

### **A. Submitter**

GIMMI GmbH  
Carl-Zeiss-Str. 6  
78532 Tuttlingen  
Germany

**JAN 27 2010**

### **B. Company contact**

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### **C. Device Name**

Trade Name: AlphaXenon Light 300 W and AlphaXenonLight 180 W  
Common Name: Light Source, Endoscopic  
Classification name: Endoscope and accessories  
Classification number: 876.1500  
Proposed Class: II  
Product Code: GCT

### **D. Pedicate/Legally Market Devices**

**Linvatec 300 W Xenon Light Source (k031994)**  
**Karl Storz Xenon Light 300 W (k962595)**  
**World of Medicine Lemke GmbH Model XL300/L5 (k021717)**

E. Device Description

AlphaXenon Light is a light generating device that when used with in conjunction with endoscopes to illuminate surgical site during Endoscopic procedures.

F. Intended Use

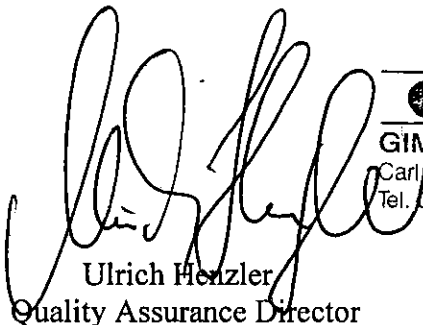
AlphaXenon Light 300W and 180W light source is used with an endoscope to provide illumination during endoscopic procedures.

G. Substantial Equivalence


AlphaXenon Light described in this notification is similar in design, technology and intended use to

The differences between AlphaXenon Light and the predicate devices are minor and raise no new questions of safety and effectiveness. Accordingly, we GIMMI GmbH believes, that the AlphaXenon Light is equivalent to the predicate devices currently on the market.


Tuttlingen December 15, 2009



Ulrich Henzler  
Quality Assurance Director



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Alexander Geisser  
Product Manager



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Ulrich Henzler  
Quality Assurance Director  
Gimmi GmbH  
Carl-Zeiss-StraBe 6  
D-78532 TUTTLINGEN  
GERMANY

JAN 27 2010

Re: K093125

Trade/Device Name: Alpha Xenon Light, 180 W and 300 W  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscopes and accessories  
Regulatory Class: II  
Product Code: GCT  
Dated: December 17, 2009  
Received: January 13, 2010

Dear Mr. Henzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

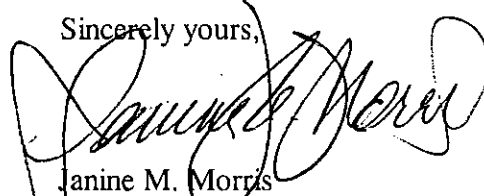
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



Abbreviated 510(k)

510(k) Number: K093125

Common Name: Light Source, Endoscope, Xenon

Device Name: AlphaXenon Light, 180 W and 300 W

Predicate Device Name: The **AlphaXenon Light** is substantially equivalent to the following predicate devices:

Linvatec 300 W Xenon Light Source (k031994)  
Karl Storz Xenon Light 300 W (k962595)  
World of Medicine Lemke GmbH, model XL300/L5 (k021717)

Classification: 21 CFR § 876.1500 Product code GCT  
Class II

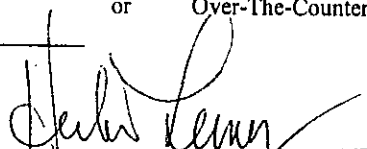
Indications for use

AlphaXenon Light 300W and 180W light source is used with an endoscope to provide illumination during endoscopic procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ or Over-The-Counter Use ☐

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K093125